

# 510(k) SUMMARY K 112006

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<b>ESTABLISHMENT REGISTRATION NUMBER:</b>	3001421318
<b>PREPARATION DATE:</b>	2011-06-30
<b>TRADE NAME:</b>	HAMILTON-TC1, model T1.
<b>COMMON NAME:</b>	Continuous Ventilator
<b>CLASSIFICATION NAME:</b>	CLASS II Ventilator, Continuous
<b>REGULATION NUMBER:</b>	21 CFR 868.5895
<b>PRODUCT CODE:</b>	CBK
<b>PREDICATE DEVICE: (PRIMARY)</b>	HAMILTON-C2 510(k) Number: K102775
<b>PREDICATE DEVICE: (SECONDARY) For airworthiness aspects</b>	DRAEGER Oxylog 3000 510(k) Number: K062267

## DEVICE DESCRIPTION

The HAMILTON-TC1 is designed for adults and pediatrics requiring invasive or noninvasive ventilation support. Due to its compact design, a fully-loaded weight of only 6.5 kg (14.3 lbs), a twin-battery supply, and a built-in turbine; the HAMILTON-TC1 can accompany a ventilated patient everywhere within the hospital or outside the hospital when transport is needed. The HAMILTON-TC1 can run using AC or DC power. It does not need compressed air or O<sub>2</sub> to drive the pneumatics, which reduces the weight load in the aircraft needed to operate the ventilator.

Since the HAMILTON-TC1 has been tested and evaluated for flight and high-altitude environments, it can be also used during patient transfer by emergency rescue vehicles, fixed-wing aircraft, or helicopter. This makes the HAMILTON-TC1 especially relevant for Aeromedical Evacuations and Medevac operations.

The HAMILTON-TC1 ventilator uses the same graphical user interface (GUI) used by the HAMILTON-C2, featuring a touchscreen "Ventilation Cockpit"; this provides the exact information that the user needs and helps focus on what is important. In addition, the HAMILTON-TC1 includes the ASV ventilation-mode which automatically applies lung-protective strategies, reduces the risk of operator error, and promotes early weaning.

The HAMILTON-TC1's microprocessor system controls gas delivery and monitors the patient. The gas delivery and monitoring functions are cross-checked by an alarm controller. This cross-checking helps prevent simultaneous failure of these two main functions and minimizes the possible hazards of software failure.

The HAMILTON-TC1 is intended as a transport ventilator, based on the existing HAMILTON-C2, with minor adaptations to make the HAMILTON-TC1 capable of being used in high-altitude flight environments. The HAMILTON-TC1's changes include the following:

1. The HAMILTON-TC1 software is identical to the HAMILTON-C2's software, except that some of the options are not available with the HAMILTON-TC1, (e.g. Neonatal Ventilation & nCPAP-PS). Other features like Trends & Loops, NIV, NIV-ST, APRV, and DuoPAP are standard with the C2, but are only optional with the HAMILTON-TC1. The software is also different since the HAMILTON-TC1 includes a DC-power inlet.
2. The HAMILTON-TC1 has increased immunity from EMI, including >30 V/m. It also has extra safety features for the EMD, ESD, and RFI environments found on aircraft.
3. The unit is contained within an impact resistant case which protects the controls from damage and inadvertent manipulation. The enclosure for the HAMILTON-TC1 has been ruggedized to withstand shock, vibrations, water ingress, and drops from >1 meter heights.
4. The HAMILTON-TC1 was tested for use in fixed and rotary-wing aircraft. Because mechanical ventilation can be challenging during air-medical transport, particularly due to the impact of changing barometric pressure with different altitude levels, the HAMILTON-TC1 automatically compensates for altitude changes. Adjusting provided- and measured-patient volumes accordingly, thereby eliminating the need for manual calculation and reducing the risk of error. This feature is similar to the Oxylog 3000.
5. The HAMILTON-TC1 has a "lock-button" which prevents an inadvertent change of settings. If screen lock is active, the following items are inactive: Touchscreen, Power/Standby switch, Print-screen key, Press-and-turn knob. Active are Alarm Silence, Manual Breath, O<sub>2</sub> enrichment, Nebulizer. To switch off power, the user must press the On/Off button for > 3 s.

## INTENDED USE

The HAMILTON-TC1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics.

### Intended areas of use:

- In the intensive care ward or in the recovery room.
- For emergency medical care or primary care.
- During transport within and outside the hospital.
- During transfer by rescue vehicles, jet or helicopter.

The HAMILTON-TC1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

## FAA REGULATIONS

In accordance with the US Department of Transportation (DOT) and the Federal Aviation Administration (FAA), along with their rules on the "Use of Respiratory Assistive Devices on Aircraft", the HAMILTON-TC1 meets the applicable safety requirements for Medical Portable Electronic Devices (M-PED) by not exceeding the maximum level of radiated radio frequency interference as described in the RTCA/DO 160F, Section 21, Category M.

## DISCUSSION ON THE NON-CLINICAL TESTS

The non-clinical test results show that the HAMILTON-TC1 is safe and effective for its intended use. The ventilator was further subjected to wave-form performance testing as described in the standard ASTM F1100-90. The data provided from these tests, were shown to be substantially equivalent to the HAMILTON-C2. The results of the software verification and validation testing demonstrate that all specified requirements have been implemented correctly and completely.

Below is a list of standards and guidance documents recognized by FDA to establish the basis of safety and effectiveness for the HAMILTON-TC1:

	Draft Reviewer Guidance for Ventilators.1995.
IEC 60601-1	General Requirements for Safety.
IEC 60601-1-2	Electromagnetic Compatibility.
IEC 60601-1-4	Programmable electrical medical systems.
IEC 60601-1-8	Alarm Systems
IEC 60601-2-12	Critical Care Ventilators.
IEC 62304	Software life-cycle processes.
IEC 62366	Application of usability engineering to medical devices.
ISO 5356-1	Conical connectors: Part 1: Cones and sockets.
AAMI/ANSI HE75	Human factors engineering. Design of medical devices.
EN ISO 14971	Application of risk management to medical devices.

Other internationally recognized standards which the HAMILTON-TC1 meets or exceeds:

RTCA/DO-160F: 2007	Environmental Conditions and Test Procedures for Airborne Equipment. Equivalent to EUROCAE/ED-14F.
Section 7	Operational Shocks and Crash Safety
Section 8	Vibration
Section 16.6	Normal surge voltage (DC). Abnormal operating conditions (DC). Low voltage conditions (DC). Abnormal surge voltage (DC).
Section 17	Voltage spikes, 28 VDC
Section 18.3.1	DC input power leads
Section 19.3.1	Magnetic field induced into equipment by the aircraft 400 Hz power systems in vicinity of the device
Section 20	Radio Frequency Susceptibility (Radiated and Conducted)
Section 21	Maximum level of conducted RF interface - Power line. Maximum level of radiated RF interface. Category M.
Section 25	Electrostatic Discharge & Radiated Electromagnetic Field

EN ISO 13485	Medical devices -- Quality management systems.
EN ISO 9001	Quality management systems.
EN ISO 5359	Low-pressure hose assemblies for use with medical gases.
EN 794-1	Particular requirements for critical care ventilators.
EN 794-3	Particular requirements for emergency and transport ventilators. Equal to EN 60068-2-6; -29; -64.
EN 1789	Medical vehicles and their equipment - Road ambulances.
EN 13718-1	Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances
IEC 62133	Battery Safety. Non-Spillable.
ASTM F1100-90	Standard Specification for Ventilators Intended for Use in Critical Care (for waveform standard analysis between the C2 and HAMILTON-TC1).
MIL-STD-461E	RS101, CS114 (curve #3), and RE101 (Army 7-cm limit).

## COMPARISON WITH THE PREDICATE DEVICES

	<b>Draeger Oxylog 3000</b> Predicate device: K062267	<b>HAMILTON-C2</b> Predicate device: K102775	<b>HAMILTON-TC1</b> (Proposed device)	<b>COMMENTS</b>
<b>Intended Use</b>	<p>Oxylog 3000 is a time-cycled, volume constant and pressure controlled emergency and transport ventilator for patients with a tidal volume from 50 mL upwards.</p> <p>The device is intended for use by trained healthcare professionals, i.e. doctors, nurses, technicians, respiratory therapists, paramedics.</p> <p>The device is intended for mobile use for emergency medical care or primary care of emergency patients:</p> <ul style="list-style-type: none"> <li>* During transport in emergency rescue vehicles or aircrafts including helicopters</li> <li>* In accident and emergency dept., in the recovery room.</li> </ul> <p>Mobile use for secondary transfers:</p> <ul style="list-style-type: none"> <li>* During transfer by road or air</li> <li>* When moving ventilated patients around in the hospital</li> </ul>	<p>The HAMILTON-C2 ventilator is intended to provide positive pressure ventilatory support to adults, pediatrics, infants, and neonates.</p> <p>Intended areas of use:</p> <ul style="list-style-type: none"> <li>• In the intensive care ward or in the recovery room.</li> <li>• During transfer of ventilated patients within the hospital.</li> <li>• During secondary transport from one hospital to another.</li> </ul> <p>The HAMILTON-C2 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.</p>	<p>The HAMILTON-TC1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics.</p> <p>Intended areas of use:</p> <ul style="list-style-type: none"> <li>• In the intensive care ward or in the recovery room.</li> <li>• For emergency medical care or primary care.</li> <li>• During transport within and outside the hospital.</li> <li>• During transfer by rescue vehicles, jet or helicopter.</li> </ul> <p>The HAMILTON-TC1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.</p>	<p>The only major difference between the C2 and the HAMILTON-TC1 is the air-worthiness aspect. Because of the different environment of use the HAMILTON-TC1 has an impact resistant case which protects the controls from damage and inadvertent manipulation.</p> <p>The HAMILTON-TC1 automatically compensates for barometric altitude changes. This feature is also found with the Oxylog 3000.</p> <p>The enclosure for the HAMILTON-TC1 has been ruggedized in accordance to the RTCA/DO 160F to withstand shock, vibrations, water ingress, and drops from &gt;1 meter heights. The HAMILTON-TC1 also has a DC-power inlet. The HAMILTON-TC1 has extra safety features for the EMD, ESD, and RFI environments found on aircraft.</p>

<b>Intended Patient Population</b>	Patients with a tidal volume from 50 to 2,000 mL.	Patients include adults, pediatrics, infants, and neonates.	Patients include adults and pediatrics.	The HAMILTON-TC1 is not intended for neonatal patients.
<b>Maximum Inspiratory Flow</b>	100 l/min	240 l/min	210 l/min	The maximum inspiratory flow for the HAMILTON-TC1 and the C2 are substantially equivalent.

The intended use statement for the HAMILTON-TC1 ventilator is comparable to both predicate devices. Technological characteristics (i.e., design, material, energy source) and performance specifications of the HAMILTON-TC1 ventilator are substantially equivalent to those of the predicate devices. The HAMILTON-C2 and the HAMILTON-TC1 have been tested for volume, flow, and pressure waveforms. A baseline waveform analysis using the specific ventilation modes was done in order to evaluate the substantial equivalence of the HAMILTON-TC1 with the HAMILTON-C2. For airworthiness and transport aspects, the HAMILTON-TC1 is substantially equivalent to the Oxylog 3000. One of the tests used to evaluate the HAMILTON-TC1 in a high-altitude, low-pressure environment, was to place the HAMILTON-TC1 inside an altitude chamber to test the effects on the sensors and the ventilator measurements & readings. The detailed protocol and successful results for this test have been included with the submission.

The intended use of the HAMILTON-TC1 is covered by the referenced predicate devices. The materials and design are also similar to the predicate devices. The technical characteristics of the HAMILTON-TC1 do not raise any new questions regarding the safety or effectiveness of ventilators. The HAMILTON-TC1's software has gone through verification/validation tests. A complete revision level history, hazard analysis, and a traceability analysis linking requirements to validation were done. The conclusions drawn from the non-clinical tests demonstrate that the HAMILTON-TC1 is as safe, as effective, and performs as well as, or better than, the legally marketed devices. The HAMILTON-TC1 is, therefore, considered to be substantially equivalent to the currently marketed predicate devices which have been previously cleared by FDA.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Mr. Ralph Aguila  
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HAMILTON MEDICAL AG  
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Bonaduz 7402  
SWITZERLAND

FEB - 9 2012

Re: K112006  
Trade/Device Name: HAMILTON-TC1  
Regulation Number: 21 CFR 868.5895  
Regulation Name: Continuous Ventilator  
Regulatory Class: II  
Product Code: CBK  
Dated: January 31, 2012  
Received: February 3, 2012

Dear Mr. Aguila:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Anthony D. Watson'.

Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



## INDICATIONS FOR USE STATEMENT

510(k) Number: \_\_\_\_\_

Device Name: HAMILTON-TC1

Indication for Use: The HAMILTON-TC1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics.

Intended areas of use:

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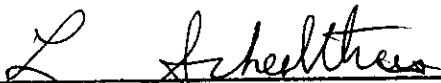
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:   K112006